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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,025	07/31/2001	Neill B. Walsdorf SR.	HO-P02490US0	3707

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EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/919,025

Applicant(s)

WALSDORF ET AL.

Examiner

Frank I Choi

Art Unit

1616

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 January 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.


Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: \_\_\_\_\_.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_



  
JOHN PAK  
PRIMARY EXAMINER  
GROUP 1600

Continuation of 2. NOTE: The proposed amendment which limits the non-glutarate calcium salts to amounts which are insufficient to neutralize gastric acidity was not set forth in the claims previously, as such, the same would require further consideration and search.

Continuation of 5. does NOT place the application in condition for allowance because: The Specification is still objected to for not providing antecedent basis for the limitation "single dose". The Specification pages and lines cited do not appear to set forth the limitation "single dose". The proposed amendment would overcome the 112nd paragraph rejection if entered. Applicant argues that CN 1210695 does not teach or suggest composition excluding non-glutarate calcium salts in amounts sufficient to neutralize gastric acidity or single dose compositions. Applicant argues that according to the definition from Dorland's that a dose is "a quantity to be administered at one time". The definition still does not define either the amount of the dose or the period of the time. As such, Applicant has not shown that the limitation excludes the prior art product. Further, the amount of non-glutarate calcium salts which would be sufficient to neutralize gastric acidity has not been defined. The burden is on Applicant to show that the amount of non-glutarate salts would be sufficient to neutralize gastric acidity. Applicant argues that the Examiner has rejected claims 1-20, 25-32 over RO 87637 in view of CN 1210695 and Remington's. However, the Office Action only rejected claims 13-20, 25-32. Applicant argues that the combined references do not teach a method orally administering to a person in need thereof a quantity of a medicinal composition of calcium glutarate sufficient to bind with phosphorous in the GI tract and inhibit phosphorous absorption. Examiner cannot but agree with said argument as the rejection only rejected the composition claims not the method claims. The proposed amendment if entered would overcome the rejection of claims 13-20, 25-32 over RO 87637 in view of the other references but only because the prior art does not teach limiting the amount of other non-glutarate calcium salts to below that sufficient to neutralize gastric acidity and not because of the other arguments set forth by Applicant. Applicant argues that the combined references do not teach single dose compositions and compounds of calcium glutarate sufficient to bind with phosphorous in the GI tract. As indicated above, the limitation "single dose" does not indicate either the amount or the period of time. In any case, Remington's clearly suggests single doses in the teaching of tablet and capsule formulations and that pharmacists will typically cut bulk liquid formulations into single prescriptions. It is well within the skill of one of ordinary skill in the art to provide formulations in single doses and one would be motivated to do so as to avoid the inconvenience of taking multiple tablets or capsules or to avoid the inconvenience of having to measure out the appropriate dose by one self. With respect to the second part of the argument, again Examiner reiterates that no amount is specifically defined and the intended use does not patentably distinguish the composition absent a showing that the amounts disclosed in the prior art would not be sufficient to bind with phosphorous in the GI tract..